Remarks

The Office Action

Applicant notes that in paragraphs 4 and 6 of the Office Action Summary ("Summary"), claim 95 is misidentified as one of the claims that is pending and currently rejected. Claim 95 was actually canceled in 2004 and claim 96, not listed in paragraphs 4 and 6 of the present Office Action, remains pending. That typographical error is carried forward from the Office Action mailed December 27, 2005, and was specifically mentioned in the first paragraph of the Remarks in Applicant's Response to Final Rejection and Request for Reconsideration dated January 12, 2006 and filed by Certificate of Mailing on January 13, 2006.

Applicant also notes that in paragraph 7 of the Summary, the typographical error "50" appears in place of "58," as is correctly stated at page 3 of the action and was also correctly stated in paragraph 7 of the Office Action Summary accompanying the action mailed December 27, 2005.

Applicant also notes that, because claim 58 is independent and because claims 59-80 each depend from claim 58, it appears that claims 58-80 should be indicated as having been "allowed" in paragraph 5 of the Summary, rather than being indicated as "allowable" in paragraph 7.

Applicant further notes that in paragraph 2(b) of the Summary, this action is correctly identified as being "non-final," whereas, in the Conclusion beginning at p. 3, the action is incorrectly stated to be "final." As previously discussed by telephone with Examiner, the basis for withdrawing the final was withdrawal of the rejection under 102(b) as asserted in the December 27, 2005, Office Action and imposition of the new rejection under 102(a).

Applicant respectfully requests permission to defer rewriting allowable claims 86 and 87, both of which depend either directly or indirectly from rejected claim 81, in independent form pending review and consideration by Examiner of the arguments

presented herein for reconsideration and withdrawal of the rejection of claim 81 under 102(a).

The Rejection

Claims 29-34, 37-42, 44-50, 52, 54-57, 81-85 and 88-95 are rejected under 102(a) as being anticipated by U.S. 5,385,551 (the '551 patent), which issued to the same applicant on January 31, 1995. Applicant respectfully traverses the rejection and requests reconsideration and withdrawal based upon the amendments and arguments presented herein.

For the rejection under 102(a) based on the '551 patent to stand, Examiner must establish that the invention as recited in the claims now rejected was "patented or described" in the '551 patent before the invention thereof by the applicant. Applicant will demonstrate in this response that the rejection fails and must necessarily be withdrawn because the claimed invention *was not patented or described* in the '551 patent.

This application is a continuation of 08/843,050 (04/25/1997), now U.S. 6,090,077; which is a CIP of 08/537,242 (09/29/1995), now U.S. 5,632,733; which is a CIP of 08/438,954 (05/11/1995), now U.S. 5,578,011. It has already been established in the Declaration of Thomas J. Shaw dated October 30, 2002, which accompanied the Amendment and Response to Office Action filed in this application by Certificate of Mailing on November 1, 2002, that he is the sole inventor of the invention claimed in the '551 patent and the sole inventor of the invention claimed in this application. That paper was filed in response to an earlier rejection of claims in this application based upon 35 U.S.C. §102(e), which was also withdrawn. Applicant notes that Examiner also previously asserted an obviousness-type double patenting rejection against the subject application based upon the '551 patent, which was also withdrawn in view of the Terminal Disclaimer in favor of the '551 patent that was executed on May 18, 2004 and filed by Certificate of Mailing dated May 19, 2004.

Applicant will show below that principal elements of the inventions recited in each presently rejected claim, some of which are amended herein, were not disclosed in the

'551 patent, but were first disclosed in the 1995 application that became the '011 patent, and were carried forward continuously into the present application. Because the all claims as presented herein recite elements that were invented by the same inventor but were not disclosed or patented in the '551 patent, the '551 patent cannot anticipate the invention as recited in the rejected claims under 35 U.S.C. §102(a).

The '551 Patent—The Locking Plunger End Cap

Prior to discussing the rejected claims, it is helpful to look at the disclosure of the '551 patent. In this patent, two syringe embodiments are disclosed, one in FIGS. 1-5 and another in FIGS. 6-9. Both embodiments are designed with a plunger having an end cap with a locking mechanism that prevents the plunger from being withdrawn after the needle has been retracted. This is desirable to avoid exposing the user to blood-borne pathogens and to prevent accidental needle stick injuries. The locking mechanism is needed because the outward periphery of the end cap on the plunger is easily graspable even after the needle is retracted (FIGS. 4 and 8). FIGS. 1-4 of the '551 patent disclose a syringe (10) having a plunger (24) with a locking end cap (56) which fits over the back end of the plunger (Col. 8, lines 62-63). End cap (56) further comprises a horizontal thumb bar (64), a circular wall (68) underlying the thumb bar, and a downwardly extending wall element (62) having radially inwardly extending projections (60) (Col. 8, line 65 to Col. 9, line 5). FIGS. 6-8 of the '551 patent disclose another embodiment of the invention—syringe (10a) having a slightly different plunger (24a) with a slightly different type of locking end cap (56a).

In the embodiment of FIGS. 6-8, no part of end cap (56a) enters the open end of hollow body (12) either before or after needle (34a) is retracted. In the embodiment of FIGS. 1-4, no part of the outer periphery of end cap (56) enters the open end of hollow body (12) either before or after needle (34) is retracted. In FIGS. 2 and 4, the lower extending portions of wall element (62) and circular wall (68) of end cap (56) are received into the barrel until circular wall (68) bottoms out in contact with annular ledge (66), but the outer periphery of end cap (56) remains outside body (12) and easily

graspable by the user, thereby necessitating the use of a locking mechanism to prevent reuse and withdrawal of the plunger after retraction.

The '551 Patent—The Needle Holder

In both embodiments of the invention disclosed in the '551 patent, prior to retraction the needle holder (94, 94a) is held in place against the biasing force of the spring (96) by closure member (30, 30a) that is mounted inside opening (20, 20a) of first end portion (14, 14a) of syringe body (12, 12a). End (90, 90a) of needle holder (84, 84a) rests in a cavity (92, 92a) of closure (30, 30a) with needle (34, 34a) extending centrally through opening (94, 94a). The front end of spring (96, 96a) is also in contact with the bottom of cavity (92, 92a). *See*, Col. 9, lines 57-64.

The Pending Application—The Recessed Plunger End Cap

The pending application claims combinations comprising principal elements that were first disclosed by Applicant in Application No. 438,954 (now U.S. 5,578,011), filed May 11, 1995, four months after the '551 patent issued. Unlike the complicated and expensive-to-manufacture locking plunger end cap as disclosed in the '551 patent, both the application of the '011 patent and the present application, which claims priority as to common subject matter from the '011 patent, disclose a syringe with a plunger having an outer periphery that is received into an opening in the back of the barrel during retraction—moving to a position where it cannot be grasped by the user. Because the end of the plunger cannot be grasped, it cannot be withdrawn again following retraction of the needle to expose the user to the needle or to blood-borne pathogens.

The pending application distinguishes the new invention over the plunger locking teeth previously disclosed in '551 patent at page 34, line 20 through page 35, line 4 (carried forward continuously from Col. 12, lines 41-51 of the '011 patent) as follows:

> There is no necessity for using internal locking teeth of any kind. No locking teeth are needed to hold the retraction mechanism or to lock the plunger after retraction. Locking teeth present difficult molding and quality control problems, tend to be temperature sensitive and tend to require a larger diameter barrel which increases premature blowout

problems. In addition to the non-reusability provided by separation of the retainer ring from the head of the needle holder and dislodgement of the stopper, the plunger is not accessible after retraction because it is depressed within an opening at the back of the outer body.

The instant application states at page 13, lines 18-22:

In the embodiment of Figure 1, outer body 12 has a collar 54 extending behind finger grips 56 having opening 58 which closely receives the outer periphery 60 of cap 48 when the plunger is depressed to the retracted position. An alternate arrangement is shown in Figures 4A and 4B in which barrel 14 is extended longitudinally, if necessary, so that end cap 48 fits closely within an opening at the back of the barrel where the finger grips are.

The specification continues at page 14, lines 1-6:

It should be noted that depending on the relationship of the inside diameter of the barrel and the diameter of the end cap, the end cap could instead be received right inside the opening at the back of the barrel. Regardless of how the end cap in back of the outer body and barrel are configured, the plunger can no longer be grasped after retraction has occurred because end cap 48 is depressed into an opening.

The Pending Application—The Spring Guide

Although the syringe disclosed in the '551 patent represented a significant improvement over syringes with retractable needles as disclosed in the prior art, Applicant also came to appreciate subsequent to filing the application for the '551 patent that those syringes embodied characteristics other than the plunger end cap discussed above that also needed improvement. Referring to Fig. 5 of the '551 patent, because of the wide space between lower end portion (14) and spring (96), spring (96) sometimes buckled outwardly into the open space as it was compressed when closure member 30 ('551, Fig. 2) was installed during manufacture. Applicant discovered a redesigned syringe barrel that enabled the needle holder to be inserted from the rear (opposite the needle end) of the syringe, thereby allowing nose (16) of the syringe barrel (Fig. 1 of instant application) to be reduced in diameter, narrowing the lateral space between the inside of the barrel and the needle holder (22). This aspect of the

invention is described at page 34, lines 5-11 of the present application (carried forward from Col. 12, lines 17-27 of the '011 patent) as follows:

> The narrow nose provides a particular advantage for mechanized assembly. The nose has a wall defining an elongated internal cavity which closely confines the spring and needle holder combination. During installation this cavity serves as a guide to steer the needle holder and uncompressed spring into a compressed state of the spring. This solves an important assembly problem. If there is much lateral space in the nose around the spring, when the uncompressed spring is being compressed, it is a laterally unstable column which flexes sideward and bunches up causing a jam up.

The Pending Application—The Forwardly Extending Needle Holder

Another structural feature of the subject device that was implemented with the narrowing of nose (16) to permit insertion of needle holder (22) from the rear (or top) of the syringe is the reduced diameter, forwardly extending portion (27) of the needle holding portion (24) of needle holder (22) as shown, for example, in Figs. 1, 2, 5 and 6 of the instant application (carried forward continuously from the same figures of the '011 patent). This forwardly extending tip of the needle holder projects beyond front (76) of nose (16) (*See*, e.g., Fig. 1 of this application), providing stable seating for needle holder (22) and permitting easy access to the front of the needle holder. This also facilitates the insertion and gluing of needle (22) into needle holder (22) after needle holder (22) is fully seated inside nose (16), thereby avoiding possibly blunting the needle while passing downwardly through the barrel and possibly partially occluding the opening in front (76) of nose (16) by trying to glue the needle into a needle holder recessed behind the front of the barrel as shown in FIG. 5 of the '551 patent.

In addition to being shown by Applicant for the first time in the drawings of the '011 patent, which are now carried forward into the present application, the following disclosure also appears in the specification text of the present application (Page 15, lines 5-6; page 20, lines 5-7; page 34, lines 16-17), having been carried forward continuously from its first introduction in the '011 patent (Col. 6, lines 48-50; col. 4, lines 45-48; col. 12, lines 34-37):

A reduced diameter portion (27) of needle holder (22) protrudes through an opening in front (76) of nose (16).

The needle does not have to be installed before the retraction mechanism is put in place because it is readily installed from the front after the needle holder is slidingly lodged in the nose.

It is not necessary to try to pass the sharp needle through an elongated body with constricted openings where slight misalignment could cause hang-ups.

The Rejected Claims—Each Recites a Structure Not Patented or Described in the '551

Seven independent claims are presently rejected: 29, 37, 45, 54, 56, 81 and 96. Each of claims 29, 37, 45, 56 and 81 (and the dependent claims depending from them) recites a combination of features that are not previously disclosed in the '551 patent. Each of those claims recites, as a principal element of the inventive combination, a plunger end cap that is receivable during retraction into an opening in the back of the syringe body. Applicant believes that each of those "end cap" claims, when read in light of the specification as set forth above in contrast to the structure disclosed in the '551 patent as set forth above, are not "patented or described" in the '551 patent as required by §102(a).

However, because end cap (56) as disclosed in the '551 patent has circular wall (68) and wall element (62) that do extend slightly into the opening in the back of the syringe body, even though thumb bar (64) cannot, Applicant has amended each of claims 29, 36, 37, 44, 45, 52, 56, 57, 81, 83 and 93 in this response to more clearly distinguish over the invention "patented or described" in the '551 patent. Each of those claims, and each of the other dependent claims depending from independent claims 29, 37, 45, 56 and 81 now recites that "the outer periphery" of the plunger end cap is received into the opening in the back of the syringe body.

Independent claims 54 and 81, and the other claims depending from them, recite as a principal element of the inventive combination a forwardly extending needle holder as described above, which clearly was not "patented or described" in the '551 patent as

detailed in the foregoing detailed explanation. Claims 54 and 55 specifically recite "wherein the needle holder has a front portion extending forwardly beyond the biasing element...." Claims 81-85 and 88-94 specifically recite "the needle holding portion extending forwardly through the first open end" of the syringe body *in combination with* "an end cap having an outer periphery receivable into the body during retraction to prevent reuse of the syringe" (discussed above).

Independent claim 96 specifically recites as a principal element of the inventive combination "the retraction assembly comprising a compressible spring, a needle holder and a retainer member continuously surrounding the need holder to hold the spring in compression prior to retraction, *the inside wall and needle holder cooperating as a spring guide during compression of the spring.*" [Emphasis supplied.] The italicized claim language, drawn from the disclosure in the specification as more fully detailed above, clearly distinguishes the syringe assembly of claim 96 from that disclosed in the '551 patent, which had wide lateral spacing between the inside wall of the syringe and the needle holder, allowing the spring to "bunch" when attempting to compress it during assembly.

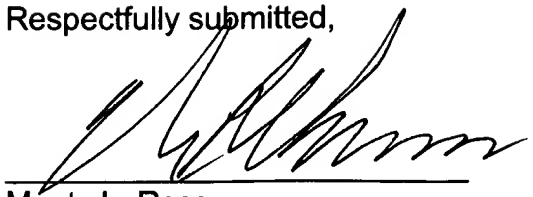
Conclusion

As amended herein, independent claims 29, 37, 45, 56 and 81, and the dependent claims depending from them (including 86 and 87, which are already said to be allowable) now clearly distinguish over the structure patented and described in the '551 patent. For reasons stated above, the other rejected claims already distinguish over the structure patented and described in the '551 patent without amendment.

All claims presently under examination are in condition for allowance and Applicant respectfully requests that the rejection be reconsidered and withdrawn and that all pending claims be passed to issue without delay.

Although no fee is believed to be required for filing this response, please charge any additional fee that may be required or credit any overpayment to Deposit Account No. 12-1781 of Locke Liddell & Sapp, LLP.

Respectfully submitted,



Monty L. Ross
Registration No. 28,899
(214) 740-8519

MLR:mr
March 10, 2006
LOCKE LIDDELL & SAPP LLP
2200 Ross Ave., Suite 2200
Dallas, Texas 75201-6776
(214) 740-8000 Telephone
(214) 756-8519 Facsimile